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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/810,904

03/26/2004

Linda S. Thomashow

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07/07/2006

USDA-ARS-OFFICE OF TECHNOLOGY TRANSFER
PATENT ADVISORS OFFICE
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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/810,904

Applicant(s)

THOMASHOW ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8 and 9 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 8 and 9 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicant argues that applicants do teach a method of obtaining a polypeptide with PhzO activity that is encoded by a nucleotide that has 50% identity with residues 89-1564 of SEQ ID NO:1, that encodes a protein having 60% identity with SEQ ID NO:2, that hybridizes under medium stringency with residues 89-1564 of SEQ ID NO:1, that is a fragment of any of these nucleotide and has at least 100 nucleotides or is 60% identical with SEQ ID NO:2. They argue that methods are given in the specification to distinguish nucleic or proteins having these identities and nucleic acids that hybridize under these conditions, and that an assay for enzymatic activity is given.

The examiner does not agree. The specification does not give guidance as to which parts of the enzyme are necessary for activity and therefore does not teach which 100 nucleotides are important. The specification also does not teach which enzymes with 60% identity or encoded by a nucleotide with 50% identity will have activity and which will not. The instant claims cover a very wide scope and it is maintained that without guidance as to specifically which nucleic acids or amino acids to change and what to change them to, and

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which nucleotides or proteins will have activity and which will not, the scope of the instant claims should be limited to what is taught in the specification. The examiner will allow claim 8(a) and (b), claim 8(e) limited to high stringency and claim 9(a). As previously stated, in order to allow for allelic variants the examiner will allow claims drawn to 95% identity.

Guo, H.H., et al. (U) teach that "the overall probability of inactivating [the human DNA repair enzyme] with a single random amino acid change occurring randomly in the protein is" about 34% or 1/3 (last sentence of the paragraph spanning columns 1-2 on page 9206. Looking at the data from Table 1, the average mutation frequencies of 2.2, 4.6 and 6.2 amino acids are shown to have a % survival of $32.7 \pm 3.5\%$, $18.2 \pm 3.3\%$ and $10.7 \pm 2.3\%$. Since it is presuming that the DNA repair enzyme must be present in order for the organism to survive, this is an indication of the % survival of enzymatic activity. Taking .66 as the % of active mutants (the reciprocal of .34), then an approximate formula of $(.66)^x \times 100\%$ shows the percentage survival of "x" random mutations. Using this formula, the results for the data in Table 1 is 40, 15 and 8, which falls within the value actually found of $32.7 \pm 3.5\%$, $18.2 \pm 3.3\%$ and $10.7 \pm 2.3\%$. Therefore this formula shows a logarithmic relationship and is a valid approximation of the amount of amino acid substitution that is allowed for an active enzyme. Of course this value could vary somewhat with different enzymes but should be valid as an approximation. In the present case, a mature protein of 491 amino acids is present and 90% identity would allow 49.1 amino acids changes. Using the formula above, this would calculate to $1.4 \times 10^{-7}\%$ active enzyme with 90% identity. 95% would calculate as $3.7 \times 10^{-3}\%$. Thus while 95% identity would require considerable experimentation to find active enzymes, it is deemed that 90% would require an inordinate amount of experimentation and with no guidance as to what specific amino

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acids to change and what to change them to, the claims should be limited to 95% identity.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

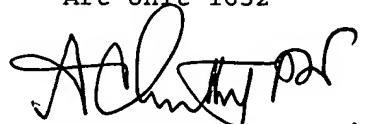
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available

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through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patterson
June 26, 2006

Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652



PONNATHAPUJACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600